DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-065/S-039 & S-040

Falcon Pharmaceuticals
c/o Alcon Research, Ltd.
Attention: Sarah J. Cantrell
Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, Texas 76134-2099

Dear Ms. Cantrell:

Please refer to your supplemental new drug applications dated June 4, 2002, received June 6, 2002, submitted under the Federal Food, Drug, and Cosmetic Act for Maxitrol (neomycin and polymyxin B sulfates and dexamethasone ophthalmic ointment). This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated April 2, June 27 and July 3, 2003. Your submissions of April 2, 2003, constituted a complete response to our March 13, 2003, action letter.

These supplemental new drug applications provide for the Puurs, Belgium facility as an alternate manufacturing site for the drug product;(b)(4)----------m as an alternate sterilization site for neomycin sulfate; a change to dexamethasone starting material source, manufacturing process and sterilization; an alternate polymycin B sulfate sterilization method; revised polymycin B sulfate, neomycin sulfate, dexamethasone and drug product specifications; an alternate container closure and revised labeling.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the enclosed labeling text submitted as final printed labeling (FPL) on November 14, 2002. The immediate container and carton labels must be identical to what was submitted June 4, 2002.

In addition, if a future labeling supplement is submitted please revise the Storage statement to read, "Store at 2º-25ºC (36º-77ºF)."

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Lori M. Gorski, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Linda L. Ng, Ph.D.
Chemistry Team Leader, for the
Division of Anti-Inflammatory, Analgesic
and Ophthalmic Drug Products, HFD-550
DNDC III, Office of New Drug Chemistry
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Linda Ng

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